REMARKS

In the September 9, 2006 Office Action, claims 19-22 were rejected as being anticipated by the disclosure in Kuberasampath (U.S. patent 5,674,844). The '844 patent suggests that a broad class of proteins *i.e.*, all morphogens can be used to treat bone loss or increase bone mass in metabolic disease. The '844 patent discloses many potential morphogens. A generic anticipation is, however, not an anticipation. *Eli Lilly v. Zenith Goldline Pharmaceutical, 05-1396, 1429-1430* (Fed. Cir. Slip. Op. December 26, 2006). Anticipation is a question of fact, including whether or not an element is inherent in the prior art. *See In re Schreiber,* 128 F.3d 1473, 1477 (Fed. Cir. 1997). To anticipate, a prior art reference must place the inventive compound or composition in the possession of the public. *In re Brown,* 329 F.2d 1006, 1011 (C.C.P.A 1964). Thus, the prior art reference must disclose each and every feature of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.,* 52 F.3d 1043, 1047 (Fed. Cir. 1995). Additionally, the "identical invention must be shown in as complete detail as is contained in the...claim". *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). The '844 claims, however, a measure of what the Applicant, in the '844 patent, was actually in possession of and the specification of the '844 patent specifically state that the morphogen is a dimeric protein. In the presently pending claims, the use of human inhibin A and inhibin B are claimed. Inhibin A and B are not dimeric proteins, rather they are heterodimeric proteins composed of different A and B subunits. This heterodimeric hormone is composed of an inhibin alpha subunit complexed with either an inhibin beta-A subunit, to form inhibin A, or an inhibin beta-B subunit, to form inhibin B. These heterodimeric proteins are not disclosed by Kuberasampath.

Additionally, the data in the '844 application supports a dimeric protein that comprises an amino acid sequence selected from the group consisting of:

(a) a sequence having at least 70% homology with the C-terminal seven-cysteine skeleton of human OP-1, residues 38-139 of SEQ ID NO: 5, and

(b) generic Sequence 6, SEQ ID NO: 31;

A sequence alignment of only the seven-cysteine skeleton of the 30-139 sequence, is shown below, comparing BMP7 (OP-1) with the Inhibin alpha subunit and the Activin beta A

subunit which when combined with the Inhibin alpha subunit comprises Inhibin A. This alignment shows that the 70% homology for the 109 aa described by the OP-1 patent is not satisfied.

```
                                10        20        30        40        50
60
                    |         |         |         |         |         |
BMP7xx0       CKKHELYVSFRDLGWQDWIIAPEGYAAYYCEGECAFPLN----SYMNATNHAIVQTLVHF
Activin       CCKKQFFVSFKDIGWNDWIIAPSGYHANYCEGECPSHIAGTSGSSLSFHSTVINHYRMRG
Inhibin       CHRVALNISFQELGWERWIVYPPSFIFHYCHGGCGLHIP----PNLSLPVPGAPPTPAQP
              * :  : :**:::**: **: * .:   **.* *   :     . :.           :
Prim.cons.    C3K33L3VSF3DLGW3DWIIAP3GY3A3YCEGEC33HI3GTSGS3LS33333I33T3333

                     70        80        90       100
                      |         |         |         |
BMP7xx0       INPETVPKPCCAPT--QLNAISVLYFDDS-SNVILKKYRNMVVRACGCH
Activin       HSPFANLKSCCVPT--KLRPMSMLYYDDG-QNIIKKDIQNMIVEECGCS
Inhibin       YSLLPGAQPCCAALPGTMRPLHVRTTSDGGYSFKYETVPNLLTQHCACI
               .  .  :.**..    :..: :   .*.  ..  :   *::.. *.*
Prim.cons.    3SP3333KPCCAPTPG3LRP3SVLY3DDGG3N3I3K333NM3V33CGC3
```

Alignment data :
Alignment length : 109
Identity (*) : 18 is 16.51 %
Strongly similar (:) : 19 is 17.43 %
Weakly similar (.) : 18 is 16.51 %
Different : 54 is 49.54 %
Sequence 0001 : BMP7xx0 (102 residues).
Sequence 0002 : Activin (106 residues).
Sequence 0003 : Inhibin (105 residues).

Applicant respectfully submits that the '844 patent does not disclose or suggest the claimed invention and that all pending claims are in condition for allowance.

Respectfully Submitted,

BUTLER, SNOW, O'MARA,
STEVENS & CANNADA

Date: 2-13-07

By: Susan B Fentress

Susan B. Fentress
Registration No. 31,327
6075 Poplar Avenue, Suite 500
Memphis, TN 38187
Telephone: 901-680-7319